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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,988	03/16/2001	Gerhard Scheuch		7304

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EXAMINER	
DAWSON, GLENN K	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/810,988	SCHEUCH ET AL.	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28-30 and 35-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28-30 and 35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05-02-2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22,25,28,29,30,31,32,35,36-39 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman, et al.-5813397.

Goodman discloses a system of a ventilator which provides doses of an aerosol according to a patient specific protocol or regimen. Either a programmable microprocessor or a canister with a readable bar label has inputted therein patient and aerosol parameters (e.g. particle size distribution, pulse length and duration) into its memory. This memory is read and used to alter or adjust the operating parameters of

the ventilator and aerosol device to provide the proper regimen. The device has the capability to detect changes in the patient's pulmonary functions or flow patterns including flow rate and tidal volumes and adjust these parameters. The inputted parameters can be requested by the microprocessor and obtained through a conventional external communications port. The operating parameters can be loaded from a library or from an external source in order to accommodate patient specific requirements. Patient parameters would inherently include any information regarding a particular patients' requirements with respect to the ventilation which is to be delivered... e.g. specifics of pressures, flow volumes, pulse durations, etc. . These would be the parameters that the system would need to perform its intended operations. Therefore, patient parameters are indeed stored into the systems memory and are used to set and then checked during use to alter the operating parameters during use to ensure that the patient was being adequately or properly ventilated. The limitation of claim 35 would be met by the timing of the ventilator with regards to pulse frequency, as any down time between inhalations as prescribed by the programming of the ventilator which would require or cause the normal inhalation-exhalation breathing cycle to include blocks (or stops) of delivering of drug until the next inhalation.

The ventilator changes or alters or adjusts its operating parameters (or the patients breathing parameters including gas flow) when it reads (based on) the patient and medication specific information downloaded to it. The respiratory flow and tidal volume that the patient breathes is automatically changed by the ventilator changing its

operating parameters. All of the valves and the compressor controls the air flow through the ventilator/aerosoliser (inhalation device).

See col. 21 lines 30-42; col. 31 line 15- col. 32 line 67; col. 34 lines 30-46; col. 35 lines 1-2 and 63-65. Additionally see abstract lines 14-21; col. 5 lines 8-24; col. 6 lines 1-33; col. 8 lines 28-47; col. 12 lines 47-53; col. 15 lines 37-55; col. 16 lines 11-27; col. 21 lines 43-52; col. 31 lines 3-14; lines 30-40,51-62; col. 31 line 67-col. 32 line 7; col. 34 lines 30-34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23,24,33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, et al.-'397 in view of Wallace, et al.-6024089.

Goodman discloses the invention as claimed with the exception of the specific inputting means.

Wallace discloses the use of manually inputting means to input patient or ventilator parameters into the ventilator. It would have been obvious to have provided manual inputs for the ventilator so that it could be used if necessary even if the memory or labels were not present. To have used a modem connected to the disclosed conventional external communications port of Goodman, would have been obvious as modems were well-known at the time of the invention to be communication devices which allowed for remote data communication.

Claims 22,24,25,28-32,34-39 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore, et al.-5931160 in view of Rapoport, et al.-5490502.

Gilmore discloses a ventilator control system and method where the system includes a user interface, a memory and a processor. The user interface allows for manual input of patient data and aerosol parameters. Upon downloading of the information which can be chosen from a set of patient-specific protocols placed in the

systems memory, the processor is able to adjust the operating parameters of the ventilator. See col. 3 lines 40-56; col. 5 lines 22-33; col. 8 lines 40-53; col. 19 lines 18-31. However, Gilmore does not disclose the inserting of a memory medium into a device of the system. However, Rapoport, et al. discloses the placing of operating parameters on a memory card for operating a ventilator. See col. 14 lines 18-20 and 50-58 and line 66 –col. 15 line 12. It would have been obvious to have used a memory card to hold the specific data needed to program the ventilator for providing proper gas administration to a particular patient as it would make the system more user friendly. The limitation of claim 35 would be met by the timing of the ventilator with regards to pulse frequency, as any down time between inhalations as prescribed by the programming of the ventilator which would require or cause the normal inhalation-exhalation breathing cycle to include blocks (or stops) of delivering of drug until the next inhalation.

The ventilator changes or alters or adjusts its operating parameters (or the patients breathing parameters including gas flow) when it reads (based on) the patient and medication specific information downloaded to it. The respiratory flow and tidal volume that the patient breathes is automatically changed by the ventilator changing its operating parameters. All of the valves and the compressor controls the air flow through the ventilator/aerosoliser (inhalation device).

Claims 23 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore, et al.-'160 in view of Rapoport, et al.-'502, as applied to the claims above, and further in view of Goodman-5813397.

Gilmore as modified by Rapoport make obvious the invention as claimed with the exception of the modem up or downlink.

Goodman discloses a system of a ventilator which provides doses of an aerosol according to a patient specific protocol or regimen. Either a programmable microprocessor or a canister with a readable bar label has inputted therein patient and aerosol parameters (e.g. particle size distribution, pulse length and duration) into its memory. This memory is read and used to alter or adjust the operating parameters of the ventilator and aerosol device to provide the proper regimen. The device has the capability to detect changes in the patient's pulmonary functions or flow patterns including flow rate and tidal volumes and adjust these parameters. The inputted parameters can be requested by the microprocessor and obtained through a conventional external communications port. See col. 21 lines 30-42; col. 31 line 15- col. 32 line 7; col. 34 lines 30-46; col. 35 lines 1-2 and 63-65. Additionally see abstract lines 14-21; col. 5 lines 8-24; col. 6 lines 1-33; col. 8 lines 28-47; col. 12 lines 47-53; col. 15 lines 37-55; col. 16 lines 11-27; col. 21 lines 43-52; col. 31 lines 3-14; lines 30-40,51-62; col. 31 line 67-col. 32 line 7; col. 34 lines 30-34.

To have used a modem connected to the disclosed conventional external communications port of Goodman, would have been obvious as modems were well-known at the time of the invention to be communication devices which allowed for remote data communication.

Goodman clearly states that the device is intended to be flexible enough to use with a specific patient by reading information concerning operating parameters (at least

aerosol parameters and most probably patient parameters) from a local or external memory source for customizing use by a specific patient. See col. 31 lines 3-14. The device can be remotely re-programmed or can rely on information on a label to change the operating parameters of the device. The code on the label causes the device to change its operating parameters. It is clear that the device is given information regarding both patient parameters and aerosol parameters, stored in memory either in a library, a microprocessor or on a label and upon reading the information, changes the operation of the device.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the original specification does not provide antecedent basis for the adjusting of a breathing parameter based on the inhalation parameters.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25,28-30 and 35-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original specification does not provide support for the adjusting of a breathing parameter based on the inhalation parameters.

Response to Arguments

Applicant's arguments filed 05-02-2007 have been fully considered but they are not persuasive.

The column and line numbers cited provide the support for the rejection as given.

The examiner is of the opinion that the claimed limitations are met because the prior art is disclosed as providing patient specific parameters onto a storage medium and it is then inputted into an inhalation device. Prior to this inputting, the inhalation device would already have a base protocol or the protocol that the previous patient used stored in its memory and the operation parameters would be set. Upon inputting the patient-specific parameters into the inhalation device, the systems have the capability to update its system by changing the operating parameters to those required by the patient-specific parameters on the medium. The inhalation device is then turned on and the drug delivery is initiated. Following this, the systems have the capability to alter the operating parameters based on sensed data received from the user. Therefore, there is an original altering of the operating parameters based on the patient protocol stored on the medium and then a continuous alteration of the operating parameters as required by the user's condition. Each of these alterings involves the adjusting of the breathing parameters of the patient by the adjusting of the ventilators parameters. The controls of the ventilator are responsible for controlling the air flow through the inhalation device.

The individual doses could be from more than one treatment period. Since different treatments and or different patient requirements would change the operating parameters, at some point the doses administered are adjusted as are the basic operating parameters of the ventilator which automatically alter the respiratory flow and tidal volume forced upon the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
29 June 2007